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The effects of system parameters on in vivo injection performance of a needle-free injector in human volunteers.

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Abstract

PURPOSE: For a novel needle-free injection (NFI) system, the relationship between frequency of wet or incomplete injections and device-related factors and subject physiological variables was examined.

MATERIALS AND METHODS: A total of 26 device configurations of a single-use pre-filled NFI system (Intraject) were used to deliver a total of 3,211 subcutaneous injections into the abdomen of 302 healthy volunteers. Two validated methods were used to determine completeness of each injection (defined as $\geq 90\%$ dose delivery). Skin-fold thickness, body mass index (BMI), Fitzpatrick skin type, sex, age, and injection site were noted for each volunteer.

RESULTS: The proportion of complete injections ranged from 59-98% among the various combinations of device configurations. Two device parameters and two subject-related variables showed strong association with injection performance; Device gas mass (chamber pressure) and orifice size demonstrated statistically significant, independent effects, with increasing gas mass and larger orifice size associated with improved injection performance. BMI and site of injection on the abdomen also demonstrated statistically significant effects with increasing BMI and lateral rather than medial injection sites associated with better injections.

CONCLUSION: Both device-related factors and subject variables interact to mediate in vivo performance of a needle-free injector.

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